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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

WEST, et al.

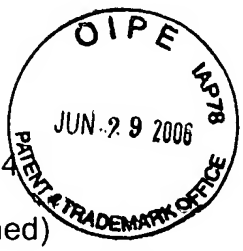
Serial No.: 10/551,202

PCT Filed: April 14, 2004

Art Unit: (not yet assigned)

Examiner: (not yet assigned)

Atty. Docket No.: 05-221-US



PHOSPHATES OF SECONDARY ALCOHOLS

Commissioner for Patents
MAIL STOP PETITIONS
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO MAKE SPECIAL
UNDER 37 C.F.R. § 1.102 (M.P.E.P. § 708.02)

Sir:

Applicants hereby petition the Commissioner to make the above-identified application special in accordance with 37 C.F.R. § 1.102(d). Pursuant to M.P.E.P. § 708.02(VIII), Applicants state the following.

(A) This Petition is accompanied by the fee set forth in 37 C.F.R. § 1.17(h).

A check in the amount of $130.00 representing the Group III petition fee is enclosed herewith.

(B) All claims are directed to a single invention.

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If the Office determines that all claims are not directed to a single invention, Applicant will make an election without traverse as a prerequisite to the grant of special status in conformity with established telephone restriction practice.

(C) A pre-examination search has been conducted.

The search was directed towards a phosphate derivative of a compound having a secondary hydroxy group, wherein said secondary hydroxy group may be chosen from pravastatin, atorvastatin, venlafaxine, their derivatives and mixtures thereof.

In particular, the search was directed towards independent claim 1, which recites a phosphate derivative of a compound selected from the group consisting of pravastatin and derivatives thereof, atorvastatin and derivatives thereof, venlafaxine and derivatives thereof and mixtures thereof.

In particular, the search was also directed towards independent claim 5, which recites a method for phosphorylating a compound having a secondary hydroxy group comprising step (a) reacting the compound having a secondary hydroxy group with P_4O_{10} in the presence of an alkali metal salt of a fatty acid.

In particular, the search was also directed towards independent claim 12, which recites a phosphate derivative comprising the reaction product of a compound having a secondary hydroxy group reacted with P_4O_{10} in the presence of an alkali metal salt of a fatty acid.

In particular, the search was also directed towards independent claim 13, which recites a phosphate derivative selected from the group consisting of [R-(R*,R*)]-2-(4-fluorophenyl)-β-phosphono-δ-hydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-*1H*-pyrrole-1-heptanoic acid, [1S-[1α(βS*, δS*),2α,6α,8β(R*),8aα]]-1,2,6,7,8,8a-hexahydro-β-phosphono-δ,6-dihydroxy-2-methyl-8-(2-methyl-1-oxobutoxy)-1-naphthleneheptanoic acid, 1-[-(dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexyl dihydrogen phosphate and mixtures thereof.

In particular, the search was also directed towards independent claim 14, which recites a phosphate derivative selected from the group consisting of 1,2-distearoyl phosphatidyl atorvastatin, 1,2-distearoyl phosphatidyl pravastatin, 1,2-distearoyl phosphatidyl venlafaxine and mixtures thereof.

The search of the above features was conducted in the following areas:

International Classes	Subclasses
C07F	9/09
C07F	9/10
C07F	9/12
C07F	9/117
A61K	9/08
A61K	31/661
A61K	31/6615
A61K	31/683
A61K	31/685
A61P	9/00
A61P	23/00
A61P	25/24

A search of the above features was also conducted in the ORBIT QUESTEL - WPAT, STN, CA, MEDLINE, and WPIDS electronic databases.

These searches were conducted by the Australian Patent Office, in its capacity as the International Search Authority for the underlying International Patent Application, Serial No. PCT/AU2004/000490, on June 9, 2004. A copy of the International Search Report summarizing the search results is attached as Exhibit A.

(D) The following is a list of the references deemed most closely related to the subject matter encompassed by the claims.

U.S. PATENT DOCUMENTS

Patent Number	Issue Date	Patentee
4299906	11/1981	

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

Document Number	Publication Date	Country or Patent Office
43870/00	12/2000	AU
1121683	7/1968	GB
2227662	8/1990	GB
2001/046204	6/2001	WO

OTHER DOCUMENTS

Author, Title, Date, Relevant Pages, Place of Publication
Derwent Abstract Accession No. 26921 K/11, SU 925961, 5/1982
Derwent Abstract Accession No. 1981-89192D/48, US 4299906, 11/1981
STN File CA, Abstract 139:399976, Puratchikody, A., et al, "Reverse Phase-High Performance Liquid Chromatographic Determination of Atorvastatin Calcium in Solid Dosage Forms", Pharma Review (2003), 1(2), 79-80, 83

A copy of each of these references (as well as other references revealed during the search) has either already been submitted earlier in prosecution of this application or is being submitted herewith in connection with the accompanying Information Disclosure Statement.

(E) It is submitted that the present invention is patentable over the references for the following reasons.

It is submitted that the cited references, whether taken individually or in combination with each other, fail to teach or suggest the invention as claimed. In particular, the cited references, at a minimum, fail to teach or suggest in combination with the other limitations recited in the claims the primary feature of the present invention as recited in independent claims 1, 5, 12, 13 and 14 of phosphates of secondary alcohols as used in the present invention.

To the extent applicable to the present Petition, Applicants submit that although the distinguishing features may represent a substantial portion of the claimed invention, the claimed invention including said feature and their inter-operation provides novel phosphates of secondary alcohols.

The references considered most closely related to the claimed invention are briefly discussed below:

AU 200043870("AU 870")

AU 870 discloses the use of a free fatty acid during phosphorylation. A free fatty acid refers to the fatty acid in its acid form and not as its alkali metal salt, therefore, the disclosure of use of a free fatty acid does not disclose or suggest the use of an alkali metal salt of a fatty acid to prevent the formation of double bonds during the phosphorylation of secondary alcohols.

Derwent Abstract Accession No. 26921 ("Derwent 26921")

Derwent 26291 discloses the use of 5% free oleic acid during phosphorylation. Oleic acid is a different chemical entity to an alkali metal salt of oleic acid, therefore, the citation does not disclose or suggest the use of alkali metal salts during the

phosphorylation process to prevent the formation of double bonds during the phosphorylation of secondary alcohols.

Derwent Abstract Accession No. 1981-89192D/48 ("Derwent 89192")

Derwent 89192 discloses the reaction of phosphorus pentoxide with the condensation product of an alkylene oxide with the reactive H in a fatty acid to produce an anionic surfactant. This citation discloses fatty acids as the entity which is being phosphorylated. This citation does not disclose or suggest the use of an alkali metal salt of a fatty acid to prevent the formation of double bonds during the phosphorylation of a secondary alcohol.

GB 1121683 ("GB 683")

GB 683 discloses the phosphorylation of a primary aliphatic alcohol, a cycloaliphatic alcohol or an ethylene glycol. The citation does not disclose or suggest the use of an alkali metal salt of a fatty acid to prevent the formation of double bonds during phosphorylation of a secondary alcohol.

STN File CA, Abstract 139:399976 ("STN 976")

STN 976 discloses the use of HPLC to determine the amount of atorvastatin calcium. The mobile phase in the ion exchange HPLC is acetonitrile and phosphoric acid. There is no disclosure in this citation that there are any phosphorylation products produced during the reaction. Further a person skilled in the art would not expect there to be phosphorylation during an HPLC determination as that would affect the accuracy of the results. Further, this citation does not disclose or suggest the use of an alkali metal salt of a fatty acid to prevent the formation of double bonds during the phosphorylation of a secondary alcohol.

WO 2001/46204 ("WO 204")

WO 204 discloses aromatic phosphonates as protein tyrosine phosphatase 1B (PTP-1B) inhibitors. This citation does not disclose phosphate derivatives of pravastatin, atorvastatin or venlafaxine.

GB 2227662 ("GB 662")

GB 662 discloses a pharmaceutical composition comprising lovastatin, pravastatin or velostatin for lowering serum cholesterol. This citation does not disclose phosphate derivatives of pravastatin, atorvastatin or venlafaxine.

Therefore, since the cited references fail to teach or suggest the above described features of the present invention as recited in each of the independent claims in combination with the other limitations recited in each of the independent claims, it is submitted that all of the claims are patentable over the cited references whether said references are taken individually or in combination with each other.

(F) Conclusion

What the Applicant considers to be a reasonable search has been conducted, though Applicant makes no representation that "better" or more relevant prior art does not exist. The United States Patent and Trademark Office is urged to conduct its own complete search of the prior art, and to thoroughly examine this application in view of the prior art cited herein and any other prior art that the United States patent and Trademark Office may locate in its own independent search. Further, while Applicant has identified in good faith certain portions of each of the references listed herein in order to provide the requisite detailed discussion of how the claimed subject matter is patentable over the references, the United States Patent and Trademark Office should not limit its review to the identified portions but rather, is urged to review and consider the entirety of each reference, and not to rely solely on the identified portions when examining this application.

In view of the foregoing, Applicant requests that this Petition to Make Special be granted and that the application undergo the accelerated examination procedure set forth in M.P.E.P. § 708.02 (VIII).

Respectfully submitted,

Dated: June 29, 2006

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